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ATTORNEY DOCKET No.: 2003946-0080 (FP04-0096-00US-XX)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Yamamoto, et. al. Examiner: NYA  
Serial No: 10/797,903 Group Art Unit: 3612  
Filing Date: March 10, 2004  
Priority Appln. No.: JP 2003-062823; filed: March 10, 2003  
JP 2003-302803; filed: August 27, 2003  
Title: c-KIT KINASE INHIBITOR

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

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November 19, 2004  
Date

Signature

Kathy Hart Gagnon  
Typed or Printed Name of person signing certificate

**TRANSMITTAL**

In regard to the above-referenced patent application, enclosed please find the following:

1. Statement Filed Pursuant To The Duty Of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98 (6 pp.);
2. Form PTO-1449 (4 pg.);
3. Cited Art (47 references);
4. Statement of Limited Recognition Under 37 CFR § 10.9(b) (1 pg.); and
5. Return-Receipt Postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,  
CHOATE, HALL & STEWART

Dated: November 19, 2004

Charles E. Lyon, D.Phil.  
Agent for Applicant  
Limited Recognition Under 37 C.F.R. §10.9(b)

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**INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 CFR §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

**Type of Statement**

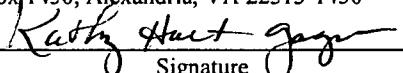
The present Information Disclosure Statement is:

An *original* Information Disclosure Statement; or  
 A *supplemental* Information Disclosure Statement.

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November 19, 2004  
Date

  
Signature

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Typed or Printed Name of person signing certificate

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

[ X ] Pursuant to 37 CFR § 1.97(b); no fee or certification is required:

[ ] Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

[ ] Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

[ X ] Before the mailing of a first Office action on the merits; or

[ ] Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

[ ] Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:

[ ] Certifies that *either*:

[ ] Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

- [ ] That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or
- [ ] Includes herewith the fee set forth in § 1.17(p).
- [ ] Pursuant to 37 CFR § 1.97(d), after the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:
- [ ] Certifies that *either*:
- [ ] Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- [ ] That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the

information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

[ ] Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

[ X ] A copy of each cited reference not indicated with a † is included;  
[ X ] Copies of references indicated with a † on the attached form PTO-1449 are not included because the requirement to provide copies was waived pursuant to USPTO OG Notice of 8/5/03.

[ ] Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

[ ] Does not contain non-English language citations;  
[ ] Includes one or more translations of a non-English citation; or  
[ X ] Does contain non-English language citations, of which the following is a concise explanation:

**English Abstract for each is provided.**

**Remarks**

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,  
CHOATE, HALL & STEWART

  
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Agent for Applicant  
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Dated: November 19, 2004



BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE  
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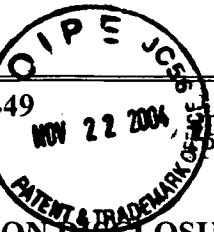
**LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)**

Charles Lyon is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of the Choate, Hall & Stewart law firm to prepare and prosecute patent applications wherein the patent applicant is the client of the Choate, Hall & Stewart law firm, and the attorney or agent of record in the applications is a registered practitioner who is a member of the Choate, Hall & Stewart law firm. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Charles Lyon ceases to lawfully reside in the United States, (ii) Charles Lyon's employment with the Choate, Hall & Stewart law firm ceases or is terminated, or (iii) Charles Lyon ceases to remain or reside in the United States on an H1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the United States Patent and Trademark Office.

Expires: December 1, 2004

  
Harry I. Moatz  
Director of Enrollment and Discipline



INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

Atty. Docket:	In re Application No. 2003946-0080 10/797,903
Applicant: Yamamoto, et al.	
Filing Date:	Group: 3612 March 10, 2004

**U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	† 4,764,454	Ichijima et al.	August 16, 1988	430	361

**U.S. PATENT APPLICATIONS**

Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Document No.	Country	Publication Date	Translation	
				Yes	No
/A.P./	EP 1 153 920	Europe	14 November 2001		
/A.P./	EP 0 870 842	Europe	14 October 1998		
/A.P./	JP 11-158149	Japan	15 June 1999	Abstract	
/A.P./	JP 2000-328080	Japan	28 November 2000	Abstract	
/A.P./	JP 09-234074	Japan	09 September 1997	Abstract	
/A.P./	JP 09-023885	Japan	28 January 1997	Abstract	
/A.P./	JP 06-153952	Japan	03 June 1994	Abstract	
	WO 04/039782	PCT	13 May 2004	Abstract	
	WO 02/032872	PCT	25 April 2002	Abstract	
	WO 01/47931	PCT	05 July 2001	Abstract	
	WO 01/47890	PCT	05 July 2001	Abstract	
/A.P./	WO 01/45689	PCT	28 June 2001		
	WO 00/43366	PCT	27 July 2000	Abstract	
/A.P./	WO 99/00357	PCT	07 January 1999		
/A.P./	WO 98/37079	PCT	27 August 1998		
	WO 97/17329	PCT	15 May 1997	Abstract	

**OTHER DOCUMENTS**

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
/A.P./	Bellone, et al., "Growth Stimulation of Colorectal Carcinoma Cells via the c-kit Receptor is Inhibited by TGF-β-1", <i>Journal of Cellular Physiology</i> , 172: 1-11, 1997.

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Applicant: Yamamoto, et al.

Filing Date: Group: 3612  
March 10, 2004

/A.P./	Berdel, et al., "Recombinant Human Stem Cell Factor Stimulates Growth of a Human Glioblastoma Cell Line Expressing c-kit Protooncogene", <i>Cancer Research</i> , <b>52</b> : 3498-3502, 1992.
/A.P./	Bussolino, et al., "Role of Soluble Mediators in Angiogenesis" <i>Eur. J. Cancer</i> , <b>32A</b> (14): 2401-2412, 1996.
/A.P./	Cohen, et al., "Expression of Stem Cell Factor and c-kit in Human Neuroblastoma", <i>Blood</i> , <b>84</b> (10): 3465-3472, 1994.
/A.P./	Deplanque, et al., "Anti-Angiogenic Agents: Clinical Trial Design and Therapies in Development", <i>European Journal of Cancer</i> , <b>36</b> : 1713-1724, 2000.
/A.P./	Folkman, J., "New Perspective in Clinical Oncology From Angiogenesis Research", <i>Eur J. Cancer</i> , <b>32A</b> (14): 2534-2539, 1996.
/A.P./	Folkman, et al., "Angiogenesis", <i>The Journal of Biological Chemistry</i> , <b>267</b> (16): 10931-10934, 1992.
/A.P./	Folkman, et al., "Clinical Applications of Research on Angiogenesis", <i>The New England Journal of Medicine</i> , <b>333</b> (26): 1757-1763, 1995.
/A.P./	Folkman, J., "What is the Evidence that Tumors are Angiogenesis Dependent?", <i>Journal of the National Cancer Institute</i> , <b>82</b> (1): 4-6, 1990.
/A.P./	Furitsu, et al., "Identification of Mutations in the Coding Sequence of the Proto-Oncogene c-kit in a Human Mast Cell Leukemia Cell Line Causing Ligand-Independent Activation of c-kit Product" <i>J. Clin. Invest.</i> <b>92</b> : 1736-1744, 1993.
/A.P./	Gokkar, et al., "Mastocytosis", <i>Lancet</i> , <b>349</b> : 1379-1385, 1997.
/A.P./	Hamel, et al., "The Road Less Travelled: c-kit and Stem Cell Factor", <i>Journal of Neuro-Oncology</i> , <b>35</b> : 327-333, 1997.
/A.P./	Hibi, et al., "Coexpression of the Stem Cell Factor and the c-kit Genes in Small-Cell Lung Cancer", <i>Oncogene</i> , <b>6</b> : 2291-2296, 1991.
/A.P./	Hines, et al., "Coexpression of the c-kit and Stem Cell Factor Genes in Breast Carcinomas", <i>Cell Growth &amp; Differentiation</i> , <b>6</b> : 769-779, 1995.
/A.P./	Hogaboam, et al., "Novel Role of Transmembrane SCF for Mast Cell Activation and Eotaxin Production in Mast Cell-Fibroblast Interactions", <i>The Journal of Immunology</i> , <b>160</b> : 6166-6171, 1998.
/A.P./	Ikeda, et al., "Changes in Phenotype and Proliferative Potential of Human Acute Myeloblastic Leukemia Cells in Culture with Stem Cell Factor", <i>Experimental Hematology</i> , <b>21</b> : 1686-1694, 1993.
/A.P./	Ikeda, et al., "Expression and Functional Role of the Proto-Oncogene c-kit in Acute Myeloblastic Leukemia Cells", <i>Blood</i> , <b>78</b> (11): 2962-2968, 1991.
/A.P./	Blume-Jensen, et al., "Activation of the Human c-kit Product by Ligand-Induced Dimerization Mediates Circular Actin Reorganization and Chemotaxis", <i>The EMBO Journal</i> , <b>10</b> (13): 4121-4128, 1991.

INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

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/A.P./	Kanakura, et al., "Expression, Function and Activation of the Proto-Oncogene c-kit Product in Human Leukemia Cells", <i>Leukemia and Lymphoma</i> , <b>10</b> : 35-41, 1993.
/A.P./	Kay, et al., "Eosinophils and Eosinophil-Associated Cytokines in Allergic Inflammation", <i>Int. Arch. Allergy Immunol.</i> <b>113</b> : 196-199, 1997.
/A.P./	Kitamura, et al., "Regulation of Development, Survival and Neoplastic Growth of Mast Cells through the c-kit Receptor", <i>Int Arch Allergy Immunol.</i> , <b>107</b> : 54-56, 1995.
/A.P./	Kolibaba, et al., "Protein Tyrosine Kinases and Cancer", <i>Biochimica et Biophysica Acta</i> , <b>1333</b> : F217-F248, 1997.
/A.P./	Kotva, et al., "Substances with Antineoplastic Activity, LIII. N-(δ-(4-Pyrrolo[2,3-d] Pyrimidinylthio) Valeryl} Amino Acids and Analogous Derivatives of Di-and Triglycine", <i>Collection Czechoslov. Chem. Commun.</i> <b>38</b> : 1438-1444, 1973.
/A.P./	Lasota, et al., "Mutations in Exons 9 and 13 of KIT Gene Are Rare Events in Gastrointestinal Stromal Tumors", <i>American Journal of Pathology</i> , <b>157</b> (4): 1091-1095, 2000.
/A.P./	Lev, et al., "A Specific Combination of Substrates is Involved in Signal Transduction by the Kit-Encoded Receptor", <i>The EMBO Journal</i> , <b>10</b> (3): 647-654, 1991.
/A.P./	Longley, et al., "Altered Metabolism of Mast-Cell Growth Factor (c-kit Ligand) in Cutaneous Mastocytosis", <i>The New England Journal of Medicine</i> , <b>328</b> (18): 1302-1307, 1993.
/A.P./	Longley, et al., "Somatic c-KIT Activating Mutation in Urticaria Pigmentosa and Aggressive Mastocytosis: Establishment of Clonality in a Human Mast Cell Neoplasm", <i>Nature Genetics</i> , <b>12</b> : 312-314, 1996.
/A.P./	Lukacs, et al., "Stem Cell Factor (c-kit Ligand) Influences Eosinophil Recruitment and Histamine Levels in Allergic Airway Inflammation", <i>The Journal of Immunology</i> , <b>156</b> : 3945-3951, 1996.
/A.P./	Meltzer, E.O., "The Pharmacological Basis for the Treatment of Perennial Allergic Rhinitis and Non-Allergic Rhinitis with Topical Corticosteroids", <i>Allergy</i> , <b>52</b> : 33-40, 1997.
/A.P./	Metcalfe, D., "Classification and Diagnosis of Mastocytosis: Current Status", <i>J. Invest. Dermatol.</i> , <b>96</b> : 2S-4S, 1991.
/A.P./	Metcalfe, et al., "Mast Cells", <i>Physiological Reviews</i> , <b>77</b> (4): 1033-1079, 1997.
/A.P./	Metcalf, et al., "Lineage Commitment in the Progeny of Murine Hematopoietic Preprogenitor Cells: Influence of Thrombopoietin and Interleukin 5", <i>Proc. Nat'l Acad. Sci. USA</i> , <b>95</b> : 6408-6412, 1998.
/A.P./	Naclerio, et al., "Rhinitis and Inhalant Allergens", <i>JAMA</i> , <b>278</b> (22): 1842-1848, 1997.
/A.P./	Nagata, et al., "Elevated Expression of the Proto-Oncogene c-kit in Patients with Mastocytosis", <i>Leukemia</i> , <b>12</b> : 175-181, 1998.
/A.P./	Natali, et al., "Breast Cancer is Associated with Loss of the c-kit Oncogene Product", <i>Int. J. Cancer</i> , <b>52</b> : 713-717, 1992.
/A.P./	Okayama, et al., "Activation of Eosinophils with Cytokines Produced by Lung Mast Cells", <i>Int Arch Allergy Immunol.</i> <b>114</b> :(suppl 1): 75-77, 1997.

Form PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2003946-0080	In re Application No. 10/797,903
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/A.P./	Okayama, et al., "Human Lung Mast Cells are Enriched in the Capacity to Produce Granulocyte-Macrophage Colony-Stimulating Factor in Response to IgE-Dependent Stimulation", <i>Eur. J. Immunol.</i> <b>28</b> : 708-715, 1998.				
/A.P./	Scheijen, et al., "Tyrosine Kinase Oncogenes in Normal Hematopoiesis and Hematological Disease", <i>Oncogene</i> , <b>21</b> : 3314-3333, 2002.				
/A.P./	Sekido, et al., "Preferential Expression of <i>c-kit</i> Protooncogene Transcripts in Small Cell Lung Cancer", <i>Cancer Research</i> , <b>51</b> : 2416-2418, 1991.				
/A.P./	Spacey, et al., "Indolocarbazoles, Potent and Selective Inhibitors of Platelet-Derived Growth Factor Receptor Autophosphorylation" <i>Biochemical Pharmacology</i> , <b>55</b> : 261-271, 1998.				
/A.P./	Strohmeyer, et al., "Expression of the <i>hst-1</i> and <i>c-kit</i> Protooncogenes in Human Testicular Germ Cell Tumors", <i>Cancer Research</i> , <b>51</b> : 1811-1816, 1991.				
/A.P./	Taniguchi, et al., "Effect of c-kit Mutation on Prognosis of Gastrointestinal Stromal Tumors", <i>Cancer Research</i> , <b>59</b> : 4297-4300, 1999.				
/A.P./	Thomas, et al., "The Eosinophil and its Role in Asthma", <i>Gen. Pharmac.</i> <b>27</b> (4): 593-597, 1996.				
/A.P./	Tian, et al., "Activating <i>c-kit</i> Gene Mutations in Human Germ Cell Tumors", <i>American Journal of Pathology</i> , <b>154</b> (6): 1643-1647, 1999.				
/A.P./	Tonary, et al., "Lack of Expression of c-KIT in Ovarian Cancers is Associated with Poor Prognosis", <i>Int. J. Cancer (Pred. Oncol)</i> <b>89</b> : 242-250, 2000.				
/A.P./	Wang, et al., "A Convenient Set of Bidentate Pyridine Ligands for Combinatorial Synthesis", <i>Tetrahedron Lett.</i> <b>40</b> : 4779-4782, 1999.				
/A.P./	Wang, et al., "The Expression of the Proto-Oncogene C-Kit in the Blast Cells of Acute Myeloblastic Leukemia", <i>Leukemia</i> , <b>3</b> (10): 699-702, 1989.				
/A.P./	International Search Report issued for related PCT application PCT/JP01/09221.				
/A.P./	International Search Report issued for related PCT application PCT/JP2004/003087				
EXAMINER	/Anna Pagonakis/		DATE CONSIDERED		12/05/2007

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.